

Totally Implanted Device for Long-Term Intravenous Chemotherapy: Experience in 123 Adult Patients With Solid Neoplasms

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Vascular access in patients receiving prolonged chemotherapy is a difficult problem. This led to the introduction of a totally implanted device. We intend to assess the efficacy of this device in a subset of oncologic patients. Between May 1989 and November 1992, 129 devices were placed in 123 adult patients with solid neoplasms. Most of the catheters were inserted by cut-down of the external jugular vein. Follow-up period ranged from 28 to 70 months. Early complications occurred in 4 of 129 implants, all in percutaneously inserted catheters. Infection was the most frequent late complication. By March 1995, 113 devices had been removed, 15 (13.3%) because of complications. Mean life of the explanted systems was 512 days. Totally implanted devices provide safe and efficient long-term venous access. Implantation should be performed by experienced surgeons, by cut-down whenever possible. Infection is the most serious complication and may be prevented by careful management. © 1996 Wiley-Liss, Inc.

KEY WORDS: central venous access, implanted device, antineoplastic treatment, complications, efficacy

INTRODUCTION

Vascular access in patients receiving antineoplastic chemotherapy often poses an important problem. Long-term treatment demands multiple venipunctures, while the irritating drugs used destroy peripheral veins, leading to a progressive decrease of available surface vessels, making venous access painful for the patient and time-consuming and frustrating for the nurse or the physician [1-6]. This can delay or prevent the administration of a planned therapy [7,8]. This has led to the search for a prolonged venous access for these patients [9-11]. During the past three decades, several methods of permanent and safe intravenous access have been developed, from arteriovenous fistulas [4,12-14] to indwelling right atrial silicone rubber catheters [4,15,16].

In 1972, Belin et al. [17] were the first to use a totally implanted venous access for intermittent hyperalimentation in children. Four years later, Fortner and Pahnke [18] reported a similar system for the cyclic administration of chemotherapeutic agents through the portal vein. Finally,

totally implanted devices, consisting of a small-volume subcutaneous injection port attached to an intravenous silicone rubber catheter, have been developed and successfully used during the past 10 years [2].

At our institution, totally implanted devices have been used since 1989 as the permanent venous access of choice for adult patients with solid neoplasms who undergo prolonged chemotherapy. This report summarizes our experience with such systems, from placement and maintenance to a close follow-up of the related complications and causes of withdrawal, in an attempt to access their long-term efficacy.

MATERIALS AND METHODS

Between May 1989 and November 1992 (43 months), 129 totally implanted devices (Port-A-Cath®, Pharmacia

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TABLE I. Primary Malignancy in 123 Patients With Totally Implanted Device for Long-Term Intravenous Chemotherapy*

Malignancy	N
Sarcoma	57
Gynecologic	22
Head and neck	18
Embryonal	12
Digestive	7
Pulmonary	4
Non-Hodgkin lymphoma	2
Urologic	2
Neuroblastoma	2
Melanoma	1

*Four patients with two synchronous neoplasms: H&N + pulmonary, 2; H&N + esophageal, 2.

Nu-Tech, Walpole, MA) were placed at our institution in 123 adult patients, 64 males and 59 females, with a mean age of 37 (range of ages: 15–72). All the patients had solid neoplasms as shown in Table I. All the devices were indicated for the administration of prolonged antineoplastic chemotherapy. Six patients had a second system placed after the first had been removed.

At the time of the procedure all the patients had more than 50,000 platelets/mm³ and more than 3,000 leukocytes/mm³, and none had an ongoing infection. No preoperative, intraoperative, or immediate postoperative antibiotic therapy was given in any case. All the procedures were done in the operating room by two teams of surgeons with wide experience in the placement of central venous access, in strict aseptic conditions, under local anesthesia and with intraoperative fluoroscopic control of the correct positioning of the tip of the catheter in the superior vena cava. Postoperatively, a chest radiograph was performed in order to confirm the position of the line.

An external jugular vein cut-down was done in 113 procedures: 99 catheters were successfully inserted. In the remaining 14 procedures the external jugular vein could not be used, either because the catheter would not advance past the external jugular vein–subclavian vein junction (8 cases), or because the external jugular vein was felt to be inappropriate for catheterization by the surgeon (6 cases); the catheters were placed through ipsilateral cut-down of the internal jugular vein. Nevertheless, all efforts were made to advance the catheter to the superior vena cava when an external jugular vein cut-down was attempted. These included careful but vigorous pushing and rotating of the catheter through the vein, gentle movements of the head of the patient toward the operative side in order to achieve a more open external jugular–subclavian venous angle, and even the use of a J-tip flexible guidewire in some extremely difficult cases, always under fluoroscopic control and with close monitoring of the electrocardiogram (ECG) and blood pressure.

Fifteen catheters were placed through the internal jugular vein (including the previously mentioned 14 external jugular vein failed attempts), 13 through the subclavian vein and 2 through the saphenous vein. Therefore, a venous cut-down was done in 115 procedures (99 external jugular, 14 internal jugular, and 2 saphenous), while 14 catheters were placed through percutaneous puncture (13 subclavian and one internal jugular).

All catheters were made of silicone, with an external diameter of 2.8 mm and a 1.0 mm lumen. All the portals were high profile (13 mm) stainless steel, with a silicone seal and a volume of 0.5 ml. All were placed in a subcutaneous pocket made in the infraclavicular space, over the pectoralis major muscle, except for the two whose catheters were inserted through the saphenous vein, which were placed in the right lower quadrant, medially to the anterosuperior iliac spine.

Subcutaneous tissue hemostasis was done with electrocoagulation and irrigations of normal saline + epinephrine 1/100,000. The thickness of subcutaneous tissue left between the portal and the skin was variable, depending on the surgeon. The portal was or was not fixed with stitches to the underlying tissue, also depending on the surgeon. The incisions in the skin were closed with interrupted 4/0 silk stitches and covered with sterile gauze. When the procedure ended all the systems were flushed with 10 ml of a solution of normal saline and 5% sodium heparin. Maintenance of the devices was done after each use or every 4–6 weeks if not in use, flushing with 10 ml of a solution of normal saline and 1% sodium heparin. All patients were followed, either through their records or by telephone. The latest control was done in March 1995, with follow-ups ranging from 28 to 70 months. Antineoplastic drugs, blood products, total parenteral nutrition (TPN), antibiotics, or other intravenous drugs, as well as colloid and crystalloid solutions, were infused through the devices without any problem.

We have not taken into consideration the number of punctures to the portal because the silicone septum may withstand 1,000–2,000 entries without tearing if a Huber-type needle is used [2,7,13,19,20], significantly exceeding the accesses a patient may receive in the course of treatment. We did not evaluate the ability to draw blood from the system.

RESULTS

All 129 systems were successfully inserted. Early complications were noted in four patients (3%): two cases of pneumothorax, one arterial puncture, and one hematoma of the subcutaneous pocket. All four catheters were placed through percutaneous puncture. No early complications were noted when catheters were placed through a cut-down procedure. Late complications were divided into infectious and noninfectious (Table II).

TABLE II. Late Complications of 129 Totally Implanted Devices for Long-Term Intravenous Chemotherapy

Complications	N/%
Infectious	
Systemic	8 (6.2)
Subcutaneous pocket	4 (3.1)
Systemic + pocket	2 (1.6)
Fever of unknown origin	1 (0.8)
Noninfectious	
Dermatitis	5 (3.9)
Catheter occlusion	2 (1.6)
Extravasation	1 (0.8)

Infectious Complications

Systemic infection was noted in 10 patients (7.75%); it is defined as the onset of fever after using the device, with positive central and peripheral blood culture for the same microorganism. *Staphylococcus epidermidis* was cultured in 7 patients, and *Staphylococcus aureus*, *Escherichia coli*, and *Candida albicans* were found once each. All patients were initially treated with intravenous vancomycin, and then with culture-specific antibiotics. Fever disappeared and blood cultures turned negative in four patients, and their devices were put back into use; all had *S. epidermidis* infections. Unresponsiveness to medical treatment led to removal of the six remaining systems; infection was confirmed when the devices were cultured. Two of the patients in whom systems were removed because of catheter-related sepsis, had a concomitant infection of the subcutaneous pocket caused by the same microorganism.

Local infection of the subcutaneous pocket without evidence of catheter-related sepsis was noted in four patients (3.1%); it is defined as a reddish, tender area that produces an exudate with positive culture. *S. aureus* was responsible in three cases, and *S. epidermidis* in one. Two patients did well with drainage of the pus and antibiotic therapy, and their devices were saved. The other two patients did not respond and their systems were withdrawn; both were infected by *S. aureus*. One patient developed fever of unknown origin (0.8%). After ruling out other possible sources of infection, the system was removed, and the fever disappeared. Although the system was not cultured, we considered the case to be a probable infection of the device.

Noninfectious Complications

Five episodes of local dermatitis and intolerance to the portal were observed in four patients (3.9%); two appeared early after implantation (at 2 and 3 months) and were very intense, and both devices had to be removed. The third patient presented a progressive intolerance to the portal 6 months after implantation; the portal was

TABLE III. Reasons for Removal of 113 Devices for Long-Term Intravenous Chemotherapy

Cause	N/%
Death of the patient	67 (60)
Completion of therapy	31 (27)
Systemic infection	4 (3.5)
Systemic + pocket infection	2 (1.8)
Pocket infection	2 (1.8)
Fever of unknown origin	1 (0.9)
Dermatitis	3 (2.7)
Catheter occlusion	2 (1.8)
Extravasation	1 (0.9)

reimplanted, extensive necrosis of the skin developed with spontaneous rejection of the device 1 month later, and the system had to be removed. The injection capsule of the fourth patient showed a tendency to erode through the skin at 8 months after placement; the device was kept in place for two more months and was withdrawn when treatment ended.

Thrombosis of the catheter was seen in two patients (1.55%) at 5 and 22 months after implantation and could not be cleared in any case with port infusion of heparin or streptokinase; therefore, both systems had to be removed.

A case of extravasation of Adriamycin, with skin necrosis, was noted in a patient 10 weeks after placement of the device (0.8%). This could not be proven to be due to leakage from the catheter by contrast studies, but the system was removed. No other system-related complications have been documented.

Twenty-three late complications related to the 129 implanted devices (17.8%) have been registered, which means one complication for every 3,388 system-days (or 0.03 complications/100 system-days). Fifteen of these (65%) have led to withdrawal of the device. There has been no system-related mortality in the series. By March 1995, 113 devices had already been removed (Table III), with a total of 57,808 days implanted, and a median of 512 days/system [15–1,857]. Sixteen devices were still functioning, with a total of 20,116 days implanted, and a median of 1,257 days/system [936–2,108].

DISCUSSION

The totally implantable subcutaneous venous access systems were designed for the administration of a wide variety of agents, including antineoplastic medication, hypertonic solutions (TPN), blood products, antibiotics, and other drugs, over a long period of time [19]. Drawing blood samples for analysis or culture is also possible through these devices. No significant differences have been found between samples drawn from the portal and from a peripheral vein, except for lactic dehydrogenase (LDH) and potassium, the values of which tend to be lower in the portal samples [20].

The advantages of these systems, when compared to the external catheters, are related to the fact they are totally implanted and therefore lack a permanent external component. This decreases the need for manipulation, reducing the risk of infection. On the other hand, these devices do not constitute a great affront to self-image and permit certain physical activities, such as swimming and showering, without any problem [21].

According to the literature, the average duration of the implanted devices varies from 85 to 353 days [3,5,7,9–11,13,19,20,22,23]. The present series shows a median duration of 512 days/system withdrawn.

In contrast with some reports [19,22,24], all devices were inserted successfully, possibly largely due to the considerable experience in central venous access of the surgeons in charge. Nevertheless, the last 25% of the devices in the series were placed by specially trained residents in General Surgery and were also successful. We therefore consider this procedure should be performed by a limited number of experienced and well-trained surgeons.

The rate of early complications was similar to that reported by others [2,8,20,22]. It is important to note that all the early complications observed in our patients occurred after placement of the catheter by percutaneous puncture. Like others [19], we recommend the insertion of the catheter to be done by surgical cut-down. Infectious complications—systemic or local, or both—were noted in 12% of our patients, signifying 0.019 infectious complications/100 system-days, which compares well with other reports with a similar follow-up [8,10,11,13,19,22,25].

Unlike other investigators [22], we did not find any relationship between the different venous accesses or the day the device was first used and the incidence of infectious complications. Prophylactic antibiotic therapy in the placement of totally implanted ports is still controversial. While some investigators give preoperative antibiotics only [8,10,11,13], others give them preoperatively and intraoperatively through the device [25], and still others use preoperative and postoperative therapy [23,26]. The study by Brothers et al. [22] compares four groups of patients: the first group was given only preoperative antibiotics, the second group received them preoperatively and postoperatively, the third group was only treated postoperatively, and the last group was given no treatment. No differences in the incidence of infectious complications were observed between the four groups [22].

Prophylactic antibiotic therapy was not used in our patients, and the incidence of infection was similar to that of the above-cited investigators. We, therefore, think that prophylactic antibiotics have no influence on the later development of infectious complications, which indeed increase when the device is not manipulated properly.

Cancer patients are usually granulocytopenic after che-

motherapy [26]. This, enhanced by their natural immunosuppression, favors infections of different types and makes it difficult to diagnose an infection that may present as fever of unknown origin. Fever in a patient with cancer is sometimes wrongly attributed to an infected device, which may be unnecessarily removed. An infection of the system is assumed when it is possible to rule out any other anatomic septic locus, and a positive blood culture is obtained both from the device and from a peripheral vein for the same microorganism. The onset of fever occurring and peaking after infusions also suggests an infection of the device.

Once the infection of the device is bacteriologically confirmed, some decisions need to be made. Some remove all the infected systems because of the difficulty in clearance [27]. Like others [4,9,13,22,26], we give vancomycin and, when available, culture-specific antibiotics through the device for 14 days. Almost one-half (40%) of the infected systems were rescued with appropriate treatment. Nevertheless, as consensus is essential, new prospectively randomized trials should be encouraged.

Local infections of the subcutaneous pocket should be treated with drainage and antibiotic therapy. Most patients do well [13,22]. In our series, 50% of the devices with pocket infection were put back into use.

Gram-positive cocci (i.e., *S. aureus* and *S. epidermidis*) are the microorganisms most frequently involved in infectious complications. Clearly behind come *Pseudomonas aeruginosa*, *E. coli*, *Klebsiella* sp., and enterococcus. The incidence of fungal infection reported varies between 0 and 38% [1,21,28]. In our series, gram-positive cocci were responsible for 86% of infections, 57% *S. epidermidis* and 29% *S. aureus*; *E. coli* and *C. albicans* account for 7% each.

The reasons for the skin problems are still unclear, but the absence of evidence of infection in the patients of our series who developed such complications seems to rule out infection as a major predisposing factor. Some other possible contributing factors have been proposed, including injury to the blood supply of the skin during the procedure or an insufficient depth of implantation of the injection capsule, but they have not been verified [20]. Furthermore, the poor nutritional status of cancer patients and the side effects of antineoplastic drugs may exacerbate skin problems [8]. Two of our patients started with a small ulcer on the scar of the subcutaneous pocket. The ulcer enlarged and the portal finally extruded. Many episodes of intolerance may be due to pressure necrosis of the underlying portal to a weak area of the skin such as the scar, favoring ulceration. We propose the subcutaneous pocket should be made wide enough for the capsule to lie comfortably and far from the scar.

The rate of catheter occlusion varies between 2% and 22% [2,3,5,7,8,10,11,13,19,20,22,23,25] and depends

mostly on the diameter of the lumen [5,7]. Dec clotting the catheter with sodium heparin or fibrinolytic agents such as streptokinase or urokinase is possible in most cases [10,23,29]. Thrombosis of the catheter was noted in two of our patients, 0.0026 episodes/100 system-days, the lowest rate reported. Both patients underwent dec clotting therapy as mentioned; nevertheless, thrombosis was detected too late, and patient flow could not be re-established in either case, so their devices had to be removed. The best treatment for catheter occlusion is prevention, with close monitoring and flushing of the device with heparinized solution after each use, or every 4–6 weeks if not used.

Drug extravasation is a rare but serious complication of the implanted devices. The primary cause seems to be a dislodgement between the needle and the silicone seal of the portal. This usually occurs in continuous infusions of 12 hr or more, often when patients are asleep and inattentive to their body position. Like others [30], we believe that these devices should be used for intermittent drug infusions of short duration (less than 2 hr). Other causes of extravasation, such as disconnection of the catheter from the portal or laceration of the silicone seal, are extremely rare. A recent report by our group [6] compares the totally implanted devices with simple small bore silicone external catheters, both for infusion of antineoplastic drugs. The mean duration of the implanted systems is five times that of the external catheters. Although the rate of infectious complications is similar for both venous access systems, the rate of mechanical complications of the external catheters is three times greater. This is not so when the implanted devices are compared to large bore silicone external catheters of the Hickman type; the rate of complications, infectious or mechanical, is even lower in this type of external catheters, although there are no significant differences [31].

CONCLUSIONS

Totally implanted injection ports are the central venous access of choice for those patients receiving long-term intravenous therapy (more than 3 months), on an outpatient basis and with infusions of short duration (less than 2 hr). Any medication or solution in common hospitalary practice can be infused, and drawing blood for cultures or analysis is usually possible. These systems are indicated especially in cancer patients with solid neoplasms, where repeated peripheral venous access may be painful for the patient, frustrating for the physician and finally impossible. The advantage of having no external component allows the patient to maintain a near-normal life-style.

The efficacy of this device is related to the period of time it can be used without complications leading to removal. According to our experience and that of others, to achieve high durability rates, a few points should be emphasized: placement by experienced surgeons under

strict aseptic conditions; open cut-down placement of the catheter when possible; careful management and periodic flushing with heparinized saline by specialized nursing staff; close follow-up evaluation of the patients for early diagnosis and treatment of complications; and cooperation of the patient and family with the physicians and nurses in charge.

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COMMENTARY

This interesting paper demonstrates the utility of the external jugular vein for the passage of a long-term intra-

venous catheter connected to a totally implanted device for long-term chemotherapy.

In the United States, the cephalic vein was used initially for cannulation through a cut-down in the deltopectoral groove. However, in a minority of patients this vein was absent or of insufficient size to be cannulated. Occasionally, although the cephalic vein was capacious enough to allow its cannulation, the catheter could not be advanced past the cephalic-subclavian vein junction. Similar experiences were noted in a few instances when the external jugular vein was used by this reviewer for cannulation. In some patients, the angle of the junction of external jugular or cephalic vein with the subclavian is such that the catheter as it goes through tends to hit the opposite wall of the vein and not to advance centrally.

The most popular route in the United States is currently the subclavian vein through direct cannulation, which is easy and safe with the available kits for insertion, including the peel-away catheters. This paper, however, indicates that with experience the external jugular vein can be an effective alternative for insertion of these catheters.

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